Application No.: 10/588,572 Docket No.: 532512001400

REMARKS

The invention is directed to an improved method to administer targeted particulate delivery vehicles which permits lower dosage and nevertheless results in better delivery of the vehicles to the intended target. This is accomplished by administering at the same time, or including in the same composition comparable particles that act as decoys to mimic the labeled targeted vehicles, thus swamping the reticuloendothelial system (RES) in the liver and spleen which would otherwise deplete the supply of targeted vehicles. This is the method of claim 1 which can be practiced using the composition of claim 11. This is outlined briefly in the first paragraph of the specification under the heading "Disclosure of the Invention."

The basis for finding lack of unity lies in an article by Ahmad, *et al.*, *Cancer Res.* (1993) 53:1484-1488, which the Examiner appears to think anticipates claim 11. It does not. Claim 11 requires a mixture of the particulate targeted vehicles mixed with an inactive carrier that comprises particulate vehicles that lack the targeting ligand. No such mixture is ever described by Ahmad. The Office states that mAb and doxorubicin are considered to be the active composition of part 1 and the lipids are the inactive carrier of part 2. This appears to overlook the fact that part 1 is a composition of particulate targeted <u>vehicles</u> that are coupled to a targeting ligand. It is not directed solely to the targeting ligand (*e.g.* mAb) and an agent (*e.g.* doxorubicin) to be delivered to the target site.

The Office is correct that Ahmad describes on page 1484 both the preparation of liposomal doxorubicin (untargeted) and mAb liposomal doxorubicin (targeted), but it does not describe a composition that contains them both. In the next description on page 1484 the animals are given

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<u>either</u> free-dox, or liposomal dox, or mAb liposomal dox or mAb liposomes. Never are these mixed together so that the liposomal dox can act as a decoy for the mAb liposomal dox.

Since Ahmad does not anticipate claim 11, Group II shares a special technical feature with Group I and the remaining claims - that technical feature is the simultaneous administration of targeted and untargeted particulate carriers wherein the untargeted particulate carriers can act as decoys for the RES.

In view of this, there is a unifying technical feature and all claims should be examined together.

As to an election of species, applicants elect halocarbon and/or hydrocarbon nanoparticles (see claim 15) the embodiment wherein both the targeted and nontargeted vehicles are the same, an active agent which is a therapeutic agent, a binding moiety which is a peptidomimetic and a binding target $\alpha_{\nu}\beta_{3}$. All of the claims in Group I read on the election of species, as do the remaining claims in Groups II-VII.

Reconsideration of the lack-of-unity finding in view of the foregoing explanation is respectfully requested and withdrawal of the requirement for election among the seven groups is also requested.

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In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit**Account No. 03-1952 referencing docket No. 532512001400.

Respectfully submitted,

Dated: October 15, 2009 By: / Kate H. Murashige /

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